REC'D 15 JUN 1998
WIPO PCT

Patents Office
45 Merrion Square
Dublin 2

OIFIG NA BPAITINNÍ + BAILE ÁTHA CLIATH +

PRIORITY DOCUMENT

I HEREBY CERTIFY that annexed hereto is a true copy of documents filed in connection with the following patent application:

Application No.	S970323
Date of filing	30 April 1997
Applicant	ESKINA DEVELOPMENTS LIMITED a British Virgin Islands company, of Vanterpool Plaza, Wickhams Cay I, P.O. Box 873, Road Town, Tortola, British Virgin Islands.

Dated this 22nd day of April, 1998

An officer authorised by the
Controller of Patents, Designs and Trademarks.

S970323

FORM NO. 1

REQUEST FOR THE GRANT OF A PATENT
PATENTS ACT, 1992

The Applicant named herein hereby request

___ the grant of a patent under Part II of the Act

_X_ the grant of a short-term patent under Part III of the Act

on the basis of the information furnished hereunder.

1. **APPLICANT**

Name Eskina Developments Limited

Address Vanterpool Plaza, Wickhams Cay I, P.O. Box 873, Road Town, Tortola, British Virgin Islands.

Description/Nationality a British Virgin Islands Company

2. **TITLE OF INVENTION**

"Spinal osteosynthesis device for mechanically interconnecting two adjacent vertebrae, in particular lumbar vertebrae"

3. **DECLARATION OF PRIORITY ON BASIS OF PREVIOUSLY FILED APPLICATION FOR SAME INVENTION (SECTIONS 25 & 26)**

Previous filing date	Country in or for which filed	Filing No.

4. **IDENTIFICATION OF INVENTOR(S)**

Name of person believed by Applicant to be the inventor

1. Mr. Harmodio Herrera

Address

1. Calle Aquilino De la Guardia, No. 8, Panama City, Republic of Panama.

5. **STATEMENT OF RIGHT TO BE GRANTED A PATENT (SECTION 17(2)(B)**

By virtue of a Deed of Assignment dated February 17, 1997

Contd./...

6. ITEMS ACCOMPANYING THIS REQUEST - TICK AS APPROPRIATE

(i) X prescribed filing fee (£55.00)

(ii) ___ specification containing a description and claims

X specification containing a description only

X Drawings referred to in description or claims

(iii) ___ An abstract

(iv) ___ Copy of previous application whose priority is claimed

(v) ___ Translation of previous application whose priority is claimed

(vi) X Authorisation of Agent (this may be given at 8 below if this Request is signed by the Applicant)

7. DIVISIONAL APPLICATION

The following information is applicable to the present application which is made under Section 24 -

Earlier Application No:
Filing Date:

8. AGENT

The following is authorised to act as agent in all proceedings connected with the obtaining of a Patent to which this request relates and in relation to any patent granted -

Name	Address
F. R. KELLY & CO.	at their address as recorded for the time being in the Register of Patent Agents

9. ADDRESS FOR SERVICE (IF DIFFERENT FROM THAT AT 8)

ESKINA DEVELOPMENTS LIMITED
F. R. KELLY & CO.

By: ______________ EXECUTIVE

Date: April 30, 1997

SPINAL OSTEOSYNTHESIS DEVICE FOR MECHANICALLY INTERCONNECTING TWO ADJACENT VERTEBRAE, IN PARTICULAR LUMBAR VERTEBRAE

The present invention relates to a spinal osteosynthesis device for interconnecting two adjacent vertebrae, in particular lumbar vertebrae, for the purpose of the fusion of their bone, comprising means for interconnecting the vertebrae in the region of their respective pedicle facets and lamina facets.

It is known that a healthy intervertebral disc constitutes a viscoelastic articular unit. It allows mobility around a longitudinal axis and its rotational movements are guided at the rear by the articular, biplanar facets in the lumbar region.

Mobility in the sagittal plane occurs in particular in the course of the flexion movements. Its control involves, in addition to the discal viscoelasticity, the limitative mechanical action of the antero-median and frontalized portion of the articular facets, thereby opposing the intersomatic shearing forces. The postero-lateral and sagittalized portion of the facets intervenes during the laterallity movements occurring in the frontal plane.

Finally, each segment of lumbar mobility is in the form of a triarticular complex in interrelation. This complex involves, in taking the L4-L5 segment as an example: the L4-L5 disc, the upper articular facets of the subjacent L5 vertebra and the lower articular facets of the

superjacent vertebra. The upper facets are directly posteriorly appendant from the L5 vertebral pedicle which is an integral part of the functional complex. The lower facets are grafted distally to the infero-lateral part of the laminae of L4. Their mean plane is orthogonal to the lamina axis.

These elements constitute a functional pair assembly disposed symmetrically on each side of the medio-sagittal plane. This assembly comprises the following succesive elements: disc, pedicle, upper and lower articular-lamina.

The posterior arch of the superjacent vertebra locks at the rear the rotational mobility of the anterior segment of the subjacent vertebra. The upper pediculo-articular assembly has for function to oppose the anterior translation of the posterior arch. In some anatomo-pathological situations, a release of these "locks" occurs. The segmental mobility lacking self-control is beyond its physiological possibilities. A reactional process attempts to remedy this failure. If unsuccessful, recourse to surgery becomes a necessary antalgic alternative.

In a first proposed type of solution, a posterior osteosynthesis of the considered spinal segment is created by using a series of pedicle screws interconnected by rods or plates, this solution being imposed in postero-lateral lumbar arthrodesis indications. The immobilization of the articulations of the fixed segment facilitates the fusion produced by a complementary bone graft.

This monoplanar synthesis neutralizes only the frontal plane. It is in fact a variant of posterior osteosyntheses initially designed for corrections of scoliosis by means of rods the anchorage of which has been rendered reliable.

These pedicle implants are situated in the sagittal plane. The cephalic mounting screws are inserted in vertebral pedicles pertaining to the functional segment adjacent to the neutralization, which are unnecessarily deteriorated thereby, which constitues a serious drawback of this type of device.

Another drawback of these arrangements resides in the frequent neo-hinging problems they create, in particular owing to the facet deteriorations above the fusioned region caused by the osteosynthesis material.

Further, the stabilization obtained is relative, since the assembly acts as a strut. The addition of transverse extra-bone interpedicle elements renders the assembly rigid by interconnecting the implants preventing the "wind-shield wiper" phenomena.

The inter-articulo-lamina grafting site is reduced since it is occupied by the plates or rods. Moreover, the radiological follow up of the fusion is difficult bearing in mind the superimpositions. Lastly, the apprenticeship of a reliable pedicle inspection is also reputed to be difficult.

It has been proposed to interconnect the articular facets by means of short transfixing screws.

This system, whose mechanical weakness is obvious, has been improved by the insertion of longer screws starting at the base of the spinous processes through the lamina, then in the interfacet manner, leading to the anterior edge of the transverse at its pedicle junction.

Such screws have definite advantages: there is obtained in this way a very satisfactory stabilization controlling the mobility about a longitudinal axis. This principle is in particular applicable in cases of instability of discal origin.

Further, the stabilization is truly mono-segmentary, the neurological risk of the procedure is very low owing to the use of a sighting device and recourse to a per-operation radiological inspection is unnecessary. The inter-tranversal decortication for preparing the bed of the graft is not obligatory, the operating time is reasonable, the apprenticeship of the technique is relatively simple, and the economic incidence of this osteosynthesis is reasonable.

On the other hand, these lumbar fixations by a translamina screw have drawbacks.

First of all, such a technique initially requires that the laminae be intact and that the facets have been respected in the course of a decompression. Further, the room for acting through the base of the transverse process is very limited. The translamina screw does not effectively oppose a force of translation, which

explains the evolutive failures.

The application of this technique to cases of facet arthropathies requires the absence of a disorientation of the facet interline of degenerative origin. This procedure cannot be applied when there is a combined translational hypermobility around the transverse and antero-posterior axes (and in particular degenerative spondylolisthesis).

The facet decortication is delicate since the sub-chondral bone must be preserved. Good results from the technique presuppose respecting the indications which are moreover very narrow.

An object of invention is therefore to propose an osteosynethesis device permitting the interconnection of the mobility segment of two adjacent vertebrae, in particular lumbar vertebrae, by avoiding the aforementioned drawbacks of the two described known embodiements.

According to the invention, the spinal osteosynthesis device for interconnecting two adjacent vertebrae comprises, for each pair of pedicle and lamina facets, a transpedicle implant, a translamina implant, and locking means for mechanically interconnecting said two implants in an angularly adjustable manner.

The invention therefore achieves a combination of two translamina and pedicle implants mechanically connected by a kind of adjustable lock.

In an advantageous embodiment, the transpedicle implant is a screw comprising a threaded shank and a head

containing a joint ball which is orientable and adapted to achieve the connection with the translamina implant.

With this device, only the pedicles concerned in this monosegmental neutralization are instrumentized, which constitues a first important advantage of the invention.

Further, the interdependence between the lamina and pedicle implants combine the mechanical advantages of the two systems, namely rotatational and translational neutralization.

The pedicle implant reinforces the anchorage in the anterior portion of the mobility segment, which is in this way reinforced and exerts a counter support. Lastly, an articular or lamina defect following on a wide releasing gesture does not prevent using this osteosynthesis procedure.

The invention also provides a device for the arthroplasty between two articular facets of two adjacent vertebrae L4, L5, one of the facets being in the extension of a pedicle of a vertebra L5 while the other facet is adjacent to a lamina of the other vertebra L4.

According to the invention, this device comprises a pedicle implant connected to a concave artificial facet, and a translamina implant connected to a convex artificial articular facet.

Further features and advantages of the invention will appear from the following description, with reference to the accompanying drawings which illustrate several

embodiments by way of non-limitative examples.

Figure 1 is a side elevational view, in a sagittal plane, to a substantially enlarged scale, of a spinal segment composed of two lumbar vertebrae equipped with a first embodiment of the osteosynthesis device according to the invention.

Figure 2 is a view of the osteosynthesis device of Figure 1 in a horizontal plane, i.e. a plane transverse to that of Figure 1.

Figure 3 is a view of the spinal segment of Figures 1 and 2 and its osteosynthesis device in a posterior frontal plane.

Figure 4 is a longitudinal sectional view, to an enlarged scale, of a pedicle screw and its orientable ball which are part of the osteosynthesis device of Figures 1 to 3.

Figure 5 is a cross-sectional view taken on line 5-5 of Figure 4.

Figure 6 is a partial cross-sectional view of a second embodiment of the osteosynthesis device according to the invention.

Figure 7 is a partly sectional and partly elevational view of a third embodiment of the osteosynthesis device according to the invention.

Figure 8 is a diagrammatic plan view of a fourth embodiment of the device according to the invention.

The spinal osteosynthesis device shown in the drawings

is adapted to mechanically interconnect two adjacent vertebrae, in particular two lumbar vertebrae L4 and L5 (Figure 1), in the region of their articular facets F, respectively of their pedicle and lamina (Figure 2), for the purpose of their subsequent bone fusion.

This device comprises, for each of the two pairs of articular facets, a transpedicle implant 1 formed by a screw having a threaded shank 2 and a head 3, a translamina implant formed by a screw 4 and means, including an orientable joint ball 5, mounted in the head 3 and adapted to permit a mechanical connection with the translamina screw associated with the transpedicle screw 1.

The head 3 is tubular and provided at its end with a member 18 set in position in the factory and in its wall with a lateral opening 6 through which there can extend an end portion 7 of the threaded shank of the translamina screw 4 which is provided with a cylindrical head 9 in this embodiment. This insertion of the end portion 7 permits screwing the latter in a diametral bore 11 in the ball 5 which is extended by a diametral tubular portion 12 coaxial with the bore 11. The latter is therefore so dimensioned as to receive the threaded end portion 7 of the corresponding screw 4 after a suitable angular orientation of the ball 5 which comes to bear against a spherical seat 13 provided in the head 13. The seat 13 extends around the base of the smooth non-tapped inner wall 3a of the head 3. Provided in the member 18 is a tapped hole which can

receive a threaded pin 14 for fixing the ball 5 in a given angular orientation. Provided in the pin 14 is a cavity 16 for the insertion of a screwing tool. The end portion of the head 3 is provided with an outer thread 17 which can receive another adaptation. The pin 14 terminates in a conical or spherical bearing surface 19 for bearing against the ball 5.

The assembly comprising the pin 14 and the member 18 constitutes a plug 15

The ball 5 with its lateral portion 12 is orientable in a horizontal plane PH, which is that of Figures 2 and 4, between a frontal plane PF and a sagittal plane PS with a predetermined range of angular movement A of the axis OS of its bore 11. Further, the ball 5 is also orientable in the frontal plane PF (plane of Figures 3 and 5) between the horizontal plane PH and the sagittal plane PS with a predetermined range of angular movement B of its axis OS. The limits of the angular movements A and B correspond to the abutment, in each of these two planes PH and PF, of the wall of the tubular portion 12 against the conical profile of the member 18 which is of course suitably dimensioned.

As a non-limitative numerical example, the angular movement A in the horizontal plane PH may be about 33°, while the angular movement B in the frontal plane PF may be about 65°. The amplitude of these angular movements is determined by the dimensions of the opening 6 of the head 3 in the horizontal and frontal planes, by the thickness of

the wall of the portion 12 and the depth to which the pin 14 is inserted in the head 3.

The edge of the opening 6 adjacent to the threaded shank 2 is defined by a profiled shape 21 for tightening the screw 1, for example a hexagonal shape; the distance between the upper face of the shape 21 and the centre O of the ball 5 may be about 2mm, this value not being intended to be limitative.

The positioning by the surgeon of this system, combining a pedicle implant 1 and a translamina implant 4 and ensuring an interlamino-pedicle locking owing to the orientable ball 5, is carried out in the following manner.

It will be understood that the surgeon first of all removes the articular facet mass of the vertebra 5 to permit disposing the head 3 of the screw 1 in its place.

a) The pedicle implant 1 is placed in position in accordance with a codified technique, namely by catheterizing the pedicle of the vertebra L5 from the isthmo-articulo-transverse junction.

b) The surgeon introduces through the opening 6 the spherical ball 5 with its portion 12 which takes up its position just in front of the upper frontal-sagittal-facet junction pertaining to the segment to be instrumentized.

c) A sighting device (known _per se_ and not shown) is adapted on the ball 5 and permits automatically guiding the introduction of the translamina implant 4 passing through the spinous process 22 of the vertebra L4. This guiding is

effected until its end portion 7 can screw into the bore 11 of the ball 5 previously correctly oriented in the horizontal and frontal planes at angles between the aforementioned values of A and B.

d) The second implant 4 penetrates at the junction of the lamina 23 and the spinous process 22 and travels in the direction of the lamina forwardly, outside and below, guided for this purpose by a specific appliance (not shown), in the direction of the centre of the lower facet of the posterior arch of this mobility segment. The implant 4 in this way automatically joins the orientable ball 5, into the bore 11 of which it extends.

e) The lock constituted by the system of the ball 5 is then actuated and thereby interconnects the two implants 1 and 4.

f) The same procedure is repeated on the contro-lateral side in order to place in position the second pair of implants 1 and 4 (Figure 2).

In a second embodiment shown in Figure 6, the device is adapted to permit providing an osteosynthesis by means of a vertebral rod 24. For this purpose, the pedicle implant 1 comprises a cage 25 which is capable of being screwed on a flange 26 of a plug 15 formed by the member 18 and the pin 14. A cylindrical member 27 inside the cage 25 is provided with a spigot 28 adapted to be introduced in the blind cavity 14a of the plug 15 and includes a semi-cylindrical recess for receiving the spinal rod 24.

The member 27 is introduced, free to rotate about its axis of revolution, from above the plug 15.

The device is completed by a second cylindrical member 30 having a semi-cylindrical recess which permits it to cap the rod 24 above member 27 and inside the cage 25. The member 30 is provided with a pivot 29 extending through an end opening 31 of the cage 25 and in this way ensures a connection between the latter and the member 30.

This pivotal connection permits an automatic positioning of the two members 25 and 30 above the rod 24 when assembling. The cage 25 is screwed on the upper flange of the plug 15 and in this way locks the rod 24 in position in the assembly.

The passage from the embodiment of Figure 4 to that of Figure 6 implies changing the plug 15, but the translamina assembly already in position is conserved.

A pathological event may result in resuming a surgical operation for extending the osteosynthesis while using the implantation of the screws 1 in the pedicles of the adjacent vertebrae; these screws are interconnected in particular by the rods 24 positioned in a plane posterior to the translamina implants. Under these conditions, and without withdrawing the implant 4, the head of the pedicle screw 1 will be capped by the cage 25 which performs the function of an extension and the plug 15 will be replaced so that the rod 24 assumes its bearing position before being locked.

This adaptability of the invention will allow the possible use of pedicle implants of which the intraspongy portion may have undergone a surface treatment suitable for rendering the anchoring reliable, by means of an osteogenic induction.

The embodiment shown in Figure 7 comprises an extension 40 which may cap the head 3 of the screw 1. This extension 40 comprises three parts: a nut 43 which is screwed on the outer thread 17 of the head 3, a body 44 engaged by its base in a floating freely rotatable manner in the nut 43, and a threaded pin 33 for the fixation of the spinal rod 24 in a U-shaped passage 45 of the body 44, which arrangement permits correctly orienting the body 44 at the end of the tightening of the nut 43.

Figure 8 illustrates another possible embodiment of the invention. In view of the fact that the pedicle axis supports in an orthogonal manner a concave upper articular facet which is articulated with a convex lower articular facet whose vertebral lamina 32 constitutes the orthogonal axis supporting it, the same principles of the technique may be used again to envisage providing a prosthetic facet arthroplasty. The pedicle implant 34 comprises, in this embodiment (Figure 8) a threaded rod surmounted not by a head but by a concave facet prosthesis 35.

The translamina implant 4 receives at its end a convex prosthetic facet 36 instead of the locked portion in the ball 5. This assembly is achieved on both pairs of facets,

the natural facets having been previously removed, as shown in the left part of Figure 8.

The two prosthetic facets 35, 36 are adapted to the support (or rod) which is respectively transpedicle 34 and translamina 4, once it has been placed in position in the manner of a cephalic sphere adapted on a prosthetic femoral rod. The interconnection may be obtained for example by clipping the facets 35, 36 onto respective spigots 37, 38 of the implants which are fitted in corresponding cavities 39, 41 of the facets 35, 36.

Various alternative embodiments of the invention may be envisaged. Thus the fixing of the ball 5 with the implants 1 and 4 may be achieved by any means equivalent to the threaded plug 15 which may be constructed in a way different from that shown. Likewise, in the device of Figure 4, the plug 15 may be set on the head 3. The angular fixation of the ball 5 may then be achieved by means of a pin screwed in a tapped bore in the solid plug 15 (Figure 4).

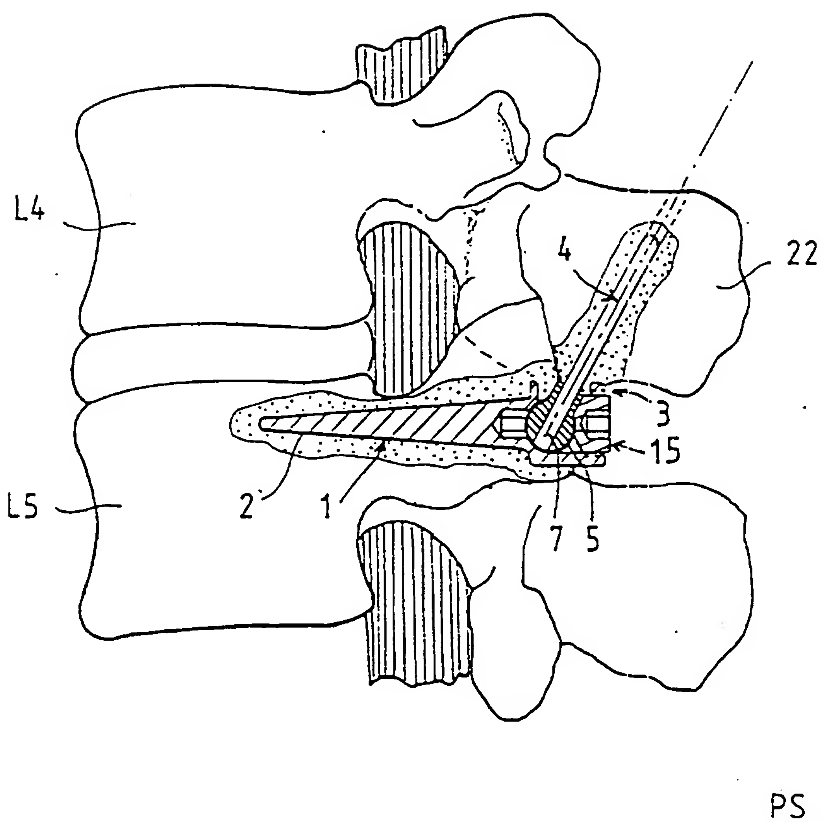


FIG.1

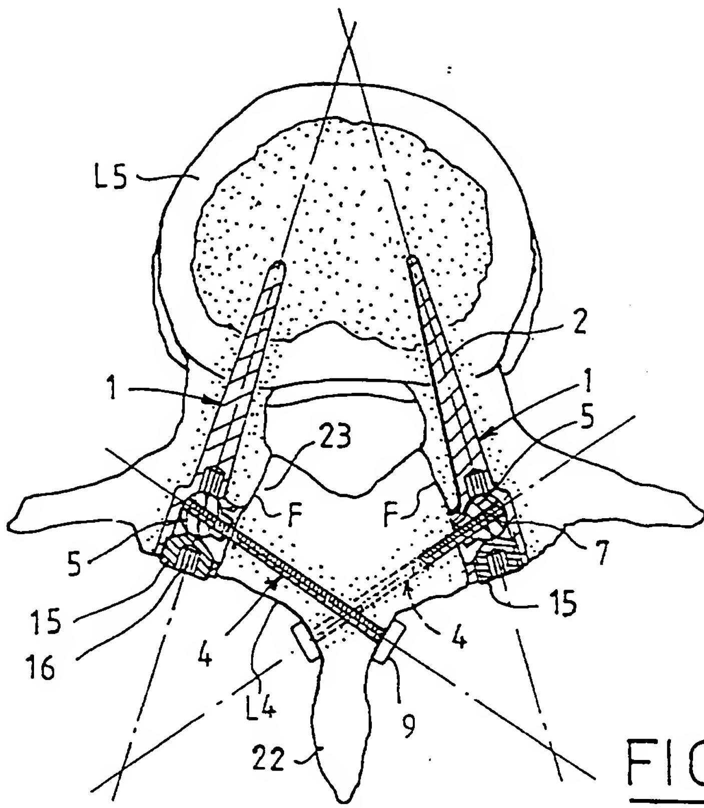


FIG. 2

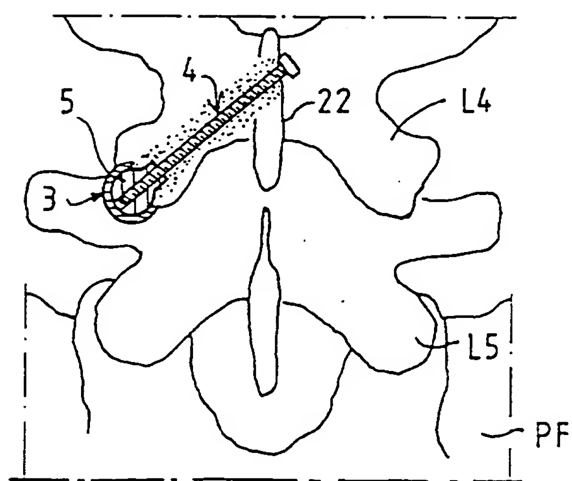
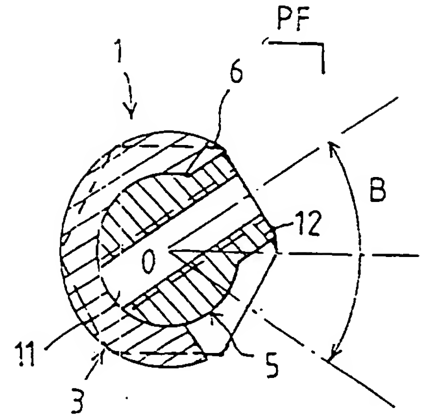


FIG. 3

FIG.5



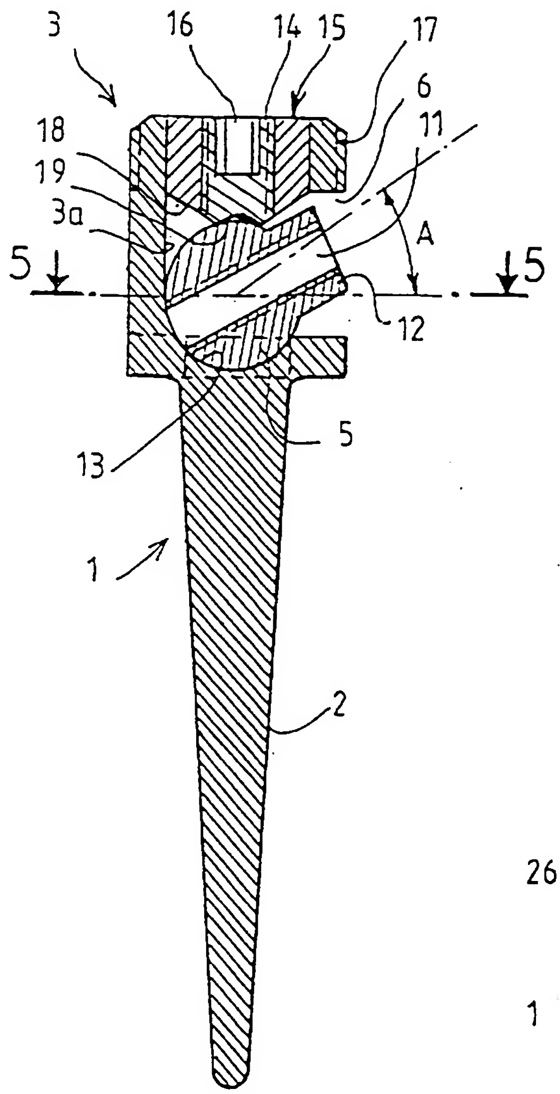


FIG.4

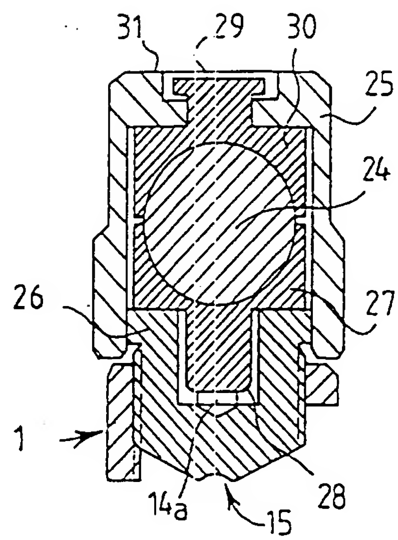


FIG. 6

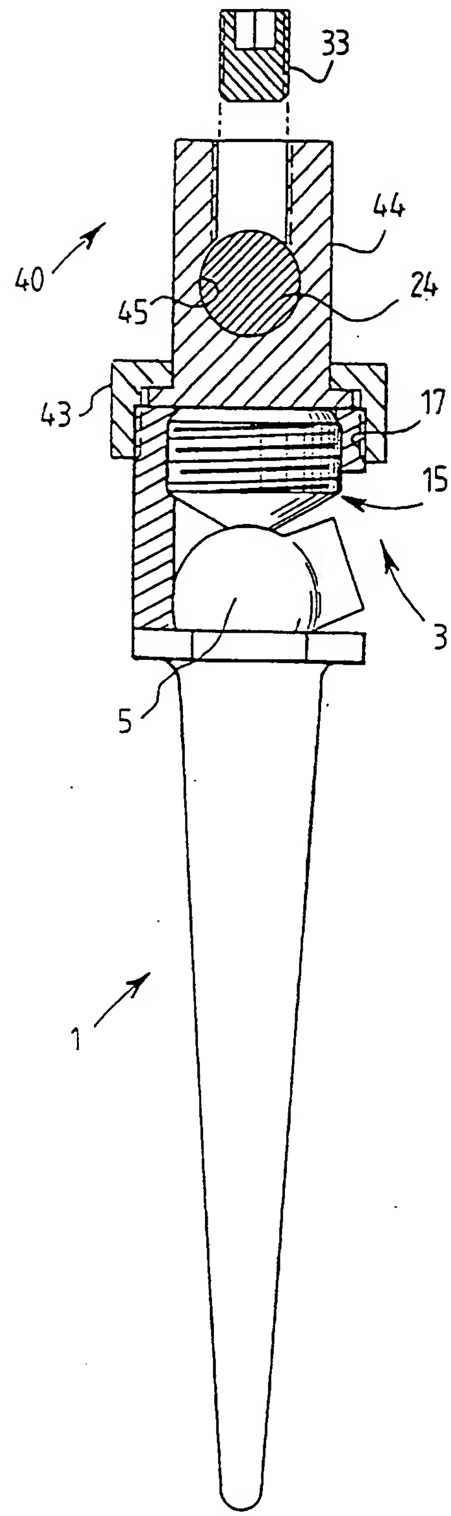


FIG. 7

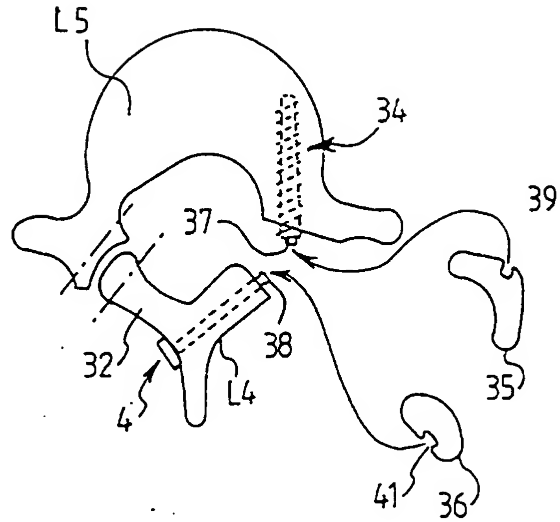


FIG. 8